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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 10/766,912 | 01/30/2004 | Carl Ernest Alexander | 4506-1025 | 2239 |
| <div>466 7590 01/15/2008</div> <div>YOUNG & THOMPSON 745 SOUTH 23RD STREET 2ND FLOOR ARLINGTON, VA 22202</div> | | | | |
| EXAMINER | | | | |
| ROBERTS, LEZAH | | | | |
| ART UNIT | | PAPER NUMBER | | |
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

| | | | |
|------------------------------|-------------------------------|----------------------------------|--|
| Office Action Summary | Application No. 10/766,912 | Applicant(s) ALEXANDER ET AL. | |
| | Examiner Lezah W. Roberts | Art Unit 1614 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 23 October 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-18 is/are pending in the application.
- 4a) Of the above claim(s) 10-12 and 14-18 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-9 and 13 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date <u>27 October 2004</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Response to Election of Species and Restriction Requirement

Claims 10-12 and 14-18 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention and species, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on August 2, 2007 and October 23, 2007.

Applicant's election with traverse of Group I and a dentifrice in the reply filed on August 2, 2007 and October 23, 2007 is acknowledged. The traversal is on the ground(s) that Group II is of course comprehended within Group I. The bead of claim 1 is not a separate invention. The pack of claim 1 requires only a bead and a packaging for the bead. The pack of claim 10 cannot be practiced with other than the bead of claim 7 by definition. Separate classification is no indication of the propriety of requirement for restriction. This is not found persuasive because the pack not only requires the bead of claim 7 but also requires a tool to use the bead of claim 7, which would require a different search. The bead may be packaged without a tool and in a bottle as previously stated by Examiner in the Requirement for Restriction mailed July 2, 2007. The beads may also be included in a carrier vehicle such as a dentifrice.

The requirement is still deemed proper and is therefore made FINAL.

Claims

Claim Objections

Claim 1 is objected to because of the following informalities: the term "the" in the eighth line, third word should be deleted. Appropriate correction is required.

Claim Rejections - 35 USC § 112 - Indefiniteness

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 6-9 and 13 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

1) Claims 6-9 recite "active ingredients characteristic of a dentifrice such as". The phrase "such as" renders the claim indefinite because it is unclear whether the limitations following the phrase are part of the claimed invention. See MPEP§ 2173.05(d). It also cannot be determined from the claim language if the claim recites the components in the alternative or if the components are in the dental care composition together.

2) Claim 13 recites "including active ingredients characteristic of a mouth freshener / oral disinfectant typically including a surface-active agent, a foam stabilizer, a disinfectant, and a flavoring agent. The phrase "typically including" renders the claim indefinite because it is unclear whether the limitations following the phrase are part of the claimed invention. See MPEP§ 2173.05(d). It also cannot be determined from the

claim language if the claim recites the components in the alternative of if the components are in the dental care composition together.

Claim Rejections - 35 USC § 102 - Anticipation

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-6 and 13 are rejected under 35 U.S.C. 102(b) as being anticipated by Baumgartner (US 2002/0048553).

Baumgartner discloses oral compositions comprising particles or capsule containing active ingredients. The invention promotes oral and dental health by encouraging children to brush longer (Abstract). Ingredients such as flavors and dye-stuff or pigments are either enclosed within capsules or bound in particles (paragraph 0006). The binding in particles encompasses the instant claims. The particles are constructed in such a way that they will only burst open through applied motion and/or pressure. The particles are made of thixotropic gels and possibly an active agent (paragraph 0012). The particles may comprise a mixture of agar and gelatine and comprise 0.5 to 2% of the particle.

The reference anticipates the instant claims insofar as it discloses a semi-solid composition suitable for use in oral or dental care comprising at least on gelling agent

providing, upon solidification, a semi-solid gel having a gel framework comprising sufficient containment means for at least one active ingredient during storage.

Claim Rejections - 35 USC § 103 - Obviousness

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to

consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-2, 5-9 and 13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Schmidt (US 5,354,551) in view of Alexander (WO 2002/026078, English Equivalent 2004/0091431).

Schmidt disclose oral care films comprising tensides, polishing agents, aromatizing agents as well as additional additives which are formulated in a binding agent or mixture of binding agents consisting of water-soluble or water-swellaable, physiologically acceptable film-forming agents. The films are pre-segmented into dosage units (Abstract). The film-forming agents include gelatins, glycerols, natural and synthetic resins and gums (col. 2, lines 28-45). Liquid components include glycerol and other components include titanium dioxide (a pigment, Example).

The reference differs from the instant claims insofar as it does not disclose the compositions are beads or that the one bead weighs one gram.

Alexander discloses dental hygiene system attractive to children, based on a free-flow toothpaste composition in the form of beads. The novel toothpaste makes a substantial contribution to reduction of environmental waste (no waste tubes) and allows the manufacture and distribution of single-unit kits for oral and especially dental hygiene (Abstract). Each bead is colored, flavored and shaped to appeal to a child. The beads are coated with a gelatin or starch capsule (paragraph 0017). The toothpaste is

released from the bead when the pressure is applied by the teeth, finger or the bristles on the toothbrush (paragraph 0064). The capsule is disposed (paragraph 0072).

The reference differs from the instant claims insofar as it does not disclose the beads are gel beads that do not comprise a coating.

It would have been obvious to one of ordinary skill in the art to have formulated bead shapes and added colors to the compositions of the primary reference motivated by the desire to make the composition more attractive to children and to promote dental hygiene to children, as disclosed by the secondary reference.

It would also have been obvious to use the film formulation to make the beads of the secondary reference motivated by the desire to use compositions that are physiologically acceptable and does not require disposal of an outer capsule layer, as disclosed by the primary reference.

In regards to the size of the bead, normally, changes in result effective variables are not patentable where the difference involved is one of degree, not of kind; experimentation to find workable conditions generally involves the application of no more than routine skill in the art. In re Aller 105 USPQ 233, 235 (CCPA 1955). It would have been obvious to one of ordinary skill in the art to have made the bead a certain size motivated by the desire to deliver an effective amount of compositions to the oral cavity that is a suitable size to use comfortably in the oral cavity, as supported by cited precedent.

Claims 1-9 and 13 are rejected.

Claims 10-12 and 14-18 are withdrawn.

No claims allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lezah W. Roberts whose telephone number is 571-272-1071. The examiner can normally be reached on 8:30 - 5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin H. Marschel can be reached on 571-272-0718. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

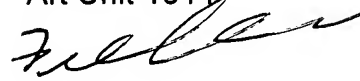
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Lezah Roberts
Patent Examiner
Art Unit 1614

A handwritten signature in cursive script, appearing to read "Leah Roberts", written in black ink.

Frederick Krass
Primary Examiner
Art Unit 1614

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